Doc Code: AP.PRE.REQ

PTO/SB/33 (07-09)
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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
PP019817.0003

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number	Filed
10/567,940	September 27, 2006

First Named Inventor
Feng Xu

Art Unit	Examiner
1632	Michael C. Wilson

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☐ attorney or agent of record.
Registration number _____.

☑ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 L0617

/Fraser D. Brown/
Signature

Fraser D. Brown
Typed or printed name

202-824-3000
Telephone number

December 20, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

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8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Conf. No. 4572
	)	
Feng Xu	)	Group Art Unit 1632
	)	
Serial No: 10/567,940	)	Examiner: Michael C. Wilson
	)	
Filed: September 27, 2006	)	Atty. Docket No. PP019817.0003

For: **INACTIVATED HOST CELL DELIVERY OF POLYNUCLEOTIDES ENCODING IMMUNOGENS**

REASONS SUPPORTING A PRE-APPEAL BRIEF REQUEST

U.S. Patent and Trademark Office
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

This paper accompanies a Pre-Appeal Brief Request for Review and a Notice of Appeal from the rejections of claims 1-13, 25, 27, 36, and 38 under 35 U.S.C. §§ 112 ¶1 and 103(a). There are legal and factual errors in these rejections.

1. The Examiner has not established a *prima facie* case that the claims are not enabled

Claim 1 is directed to administering a bacterial host cell which comprises a polynucleotide encoding an immunogen. The polynucleotide is within the host cell genome, within a plasmid, or within a replicon. The Examiner asserts it would require undue experimentation to use any "polynucleotide, specifically linear strands of non-

plasmid DNA, RNA replicons (DNA or RNA) or any virus including retrovirus." Office Action mailed June 23, 2010 at page 3.

A simple assertion does not shift the burden to the applicants of providing evidence that the claims are enabled. Rather, the Examiner bears the burden of establishing that practicing the full scope of the claimed subject matter would have required undue experimentation. *In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993). The Office must not only explain why it doubts the statements in the specification's supporting disclosure, but also must support its assertions "with acceptable evidence or reasoning which is inconsistent with the contested statement." *In re Marzocchi*, 439 F.2d 220, 224 (C.C.P.A. 1971).

Here, the rejection is legally insufficient because the Examiner provided neither evidence nor reasoning to support the assertion that the claims are not enabled.

Moreover, the claims are enabled for their full scope. The specification is addressed to those skilled in the art and need not provide knowledge which is generally known by those skilled in the art. *Hybritech Inc. v. Monoclonal Antibodies, Inc.,* 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986); *Genentech Inc. v. Novo Nordisk A/S*, 42 U.S.P.Q.2d 1001, 1005 (Fed. Cir. 1997). Preparing bacteria harboring polynucleotides encoding immunogens integrated in the genome, within a plasmid, or within a replicon is old technology in the art. In addition, pages 7 to 9 provide examples of immunogens from bacteria such as *Neiserria meningitides*, parasites such as *plasmodia falciparum*, and viruses such as HIV. Particular HIV proteins are also identified; for example, gag, env, pol, tat, nef, rev, vpu. One of ordinary skill in the art could readily make and use bacteria containing polynucleotides encoding these immunogens integrated in the genome, within

a plasmid, or within a replicon.

The rejection is legally inadequate and should be withdrawn.

2. The Examiner did not properly consider the declaration submitted to antedate Xu in response to the rejections under 35 U.S.C. § 103(a)

Both obviousness rejections rely on Xu[1] as primary reference. Applicants provided a declaration under 37 C.F.R § 1.131 of the sole inventor, Dr. Feng Xu, with the response filed November 25, 2009 to establish the Xu reference is not prior art to the present application. The Examiner erroneously maintains the declaration is defective.

First, the Examiner asserts the declaration is defective because the "statement in paragraph 3 is not as broad as the claims or the teachings of Xu." Office Action at page 5. Citing *In re Wakefield*, 422 F.2d 897 (CCPA 1970), M.P.E.P § 715.02 (8th Edn., Sept 2007) states that:

> If the affidavit contains facts showing a completion of the invention commensurate with the extent of the invention as claimed is shown in the reference or activity, the affidavit or declaration is sufficient, whether or not it is a showing of the identical disclosure of the reference or the identical subject matter involved in the activity.

The Xu reference shows administering attenuated bacteria containing plasmids to express an antigen and induce an immune response. The declaration establishes that Applicant administered heat-killed bacteria containing plasmids to express an antigen and induce an immune response before Xu's publication date. The declaration provides sufficient evidence to antedate Xu.

[1] Xu *et al.*, "Immunogenicity of an HIV-1 gag DNA vaccine carried by attenuated Shigella," Vaccine. 2003 Jan 30;21(7-8):644-8.

Second, the Examiner contends that the declaration "does not teach the bacteria used prior to 10-25-02 were heat killed." Dr. Xu states that the "[b]acterial cells were heat killed" at ¶ 5 of the Declaration.

Third, the Examiner contends that it is not clear that the results described in paragraphs 4-5 were obtained before October 25, 2002. Dr. Xu states all work described in the declaration was performed before October 25, 2002 at ¶ 2 of the Declaration.

Fourth, the Examiner asserts the declaration is defective because it "does not provide notebook dates for the data." Office Action at page 5. There is no requirement that a declaration under 37 C.F.R. § 1.131 provide dates. The applicant may "merely allege that the acts referred to occurred prior to a specified date." M.P.E.P. § 715.07 II (8th ed. 2007).

Finally, the Examiner contends the declaration is defective because the "declaration does not address the fact that there were co-authors on the Xu reference that appear to have contributed to the claimed invention." Office Action at page 5. A declaration under 37 C.F.R. § 1.131 to antedate a cited reference does not require the declarant to address co-authors of a paper. A 37 C.F.R. § 1.131 declaration overcomes a prior art rejection by proving invention of the claimed subject matter by Applicant *prior* to the effective date of the reference or activity relied upon in the rejection. M.P.E.P. § 715.01(8th ed. 2007). Here, Applicant has properly sworn behind the Xu reference.

Absent the Xu reference, the obviousness rejections cannot stand and should be withdrawn.

Respectfully submitted,
BANNER & WITCOFF, LTD.

/Fraser D. Brown/

Date: December 20, 2010 By: _____

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202-824-3000